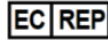




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iTero Lumina™ Scanner Sleeves Instructions for Use

The following symbols may appear on the iTero Lumina scanner sleeves packaging:

	CAUTION: Rx Only. US Federal Law restricts this device to sale by or on the order of a licensed Dentist, Orthodontist, or Dental Professional. The system serves as a prescription medical device and should be operated by trained dental health-care providers only.		
	Medical device manufacturer.	Consult the instructions/electronic instructions for use.	Authorized representative in the European Community.
	CE mark.	Country of manufacture (including date of manufacture).	Use-by date.
	Keep away from direct sunlight.	Catalogue number.	Unique device identifier.
	Temperature limit.	Do not re-use.	Medical device.
	Keep dry.	Batch code.	Quantity.



Safety Instructions:

- **Warning:** The iTero Lumina sleeves are intended for single use only. Do not reuse.
- **Warning:** The iTero Lumina sleeves are intended for single use and must be disposed of and replaced after each patient in order to reduce the risk of cross-contamination.
- **Warning:** To reduce the risk of cross-contamination, it is essential that the iTero Lumina scanner is fully cleaned and disinfected immediately after each patient, and that the iTero Lumina sleeve is replaced between patients, as described in the *iTero Lumina User manual*.
- **Warning:** If you notice any damage, do not use the iTero Lumina sleeves and contact Customer Support.
- **CAUTION:** Do not use the iTero Lumina sleeves after the expiry date.
- **CAUTION:** Dispose of iTero Lumina sleeves according to standard operating procedures or local regulations for disposal of contaminated waste.
- iTero Lumina sleeves are supplied as non-sterile and should not be sterilized before usage.
- iTero Lumina sleeves comply with the applicable parts of ISO 10993 Biocompatibility international standard.

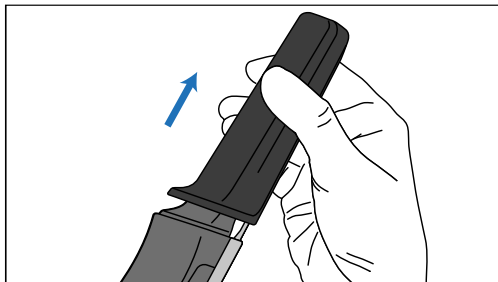
iTero Lumina sleeves are suitable for the iTero Lumina family of products. They are a single use disposable component intended for use as a cover to the iTero Lumina scanner wand tip to reduce the risk of cross-contamination and to protect the optical window of the wand during the scanning procedure.

iTero Lumina sleeves may be used on patients classified as Children, Adolescents, and Adults.

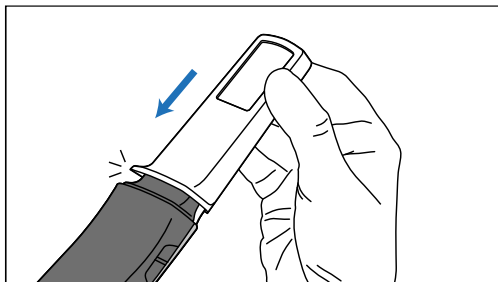
Any serious incidents in relation to the iTero™ device should be reported to Align Technology Ltd. and the competent authority of the Member State in which the user and patient are established.

Applying a sleeve:

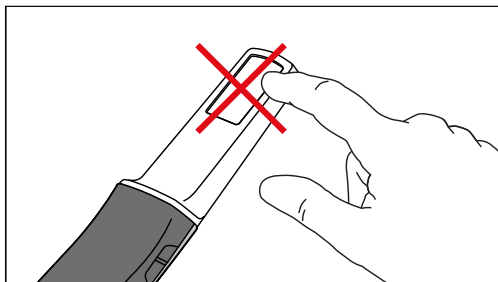
- 1) Gently remove the dark protective sleeve from the wand.



- 2) Gently slide a new sleeve onto the tip of the wand until it clicks into place.

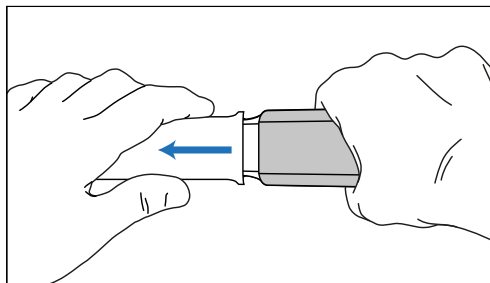


Note: Do not touch the sleeve window.



Removing the sleeve

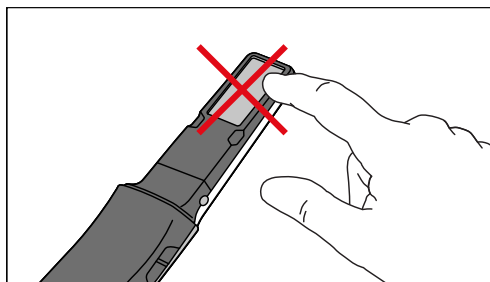
- 1) Once the scan is complete, or if the scan has been interrupted, slowly pull the sleeve off the wand, and discard it.



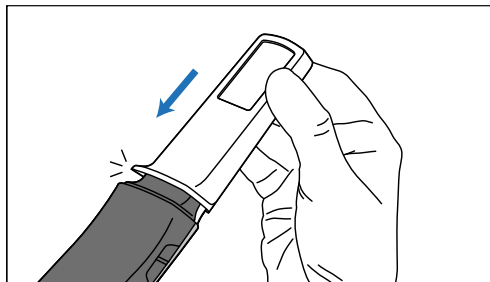
Note: OPTICAL SURFACE

DO NOT touch the optical surface of the wand. Contact may cause damage.

If additional cleaning, besides that listed in the *iTero Lumina User manual* is necessary, use the anti-static cloth found inside the sleeve box.



- 2) Disinfect the wand, as described in the *iTero Lumina User manual*.
- 3) Gently slide a new sleeve onto the tip of the wand until it clicks into place.



Note: If the scanner will not be used immediately after cleaning and disinfection, attach the dark protective sleeve.

Refer to our website www.itero.com to learn how the iTero Service can enhance your business by increasing patient satisfaction, improving clinical care, and enhancing office efficiency.

